

**United States Department of Agriculture
Agricultural Marketing Service, Science & Technology
Pesticide Data Program**

SOP No.: PDP-DATA-04		Page 1 of 7
Title: Data Submission, Storage, Retrieval, and Archival		
Revision: 7	Replaces: 10/1/98	Effective: 04/01/01

1. Purpose:

To provide standard procedures for data submission, storage, retrieval, and archival for laboratories participating in the USDA/AMS Pesticide Data Program (PDP).

2. Scope:

This standard operating procedure (SOP) shall be followed by all laboratories conducting residue studies for PDP, including support laboratories conducting stability or other types of studies that may impact the program.

3. Outline of Procedure:

- 5.1 Data Package Contents
- 5.2 Data Submission
- 5.3 Data Storage
- 5.4 Data Archival at the Participating Laboratory
- 5.5 Storage in Federal Record Centers

4. References:

- USDA/AMS PDP Quality Assurance(QA)/Technical Meeting, February 21-22, 2001
 - Quality Assurance (QA) Committee Meeting, May 19-21, 1998
 - Memorandum, Procedures of Data Storage for the USDA/AMS Pesticide Data Program, May 25, 1994
 - 40 CFR 160.190, Storage and Retrieval of Records and Data
 - Minutes, PDP Federal/State Meeting, July 18, 1991
 - ISO/IEC Guide 25: 1990 (E) General Requirements for the Competence of Calibration and Testing Laboratories
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5. Specific Procedures:

This standard operating procedure represents minimum PDP requirements and is presented as a general guideline. Each laboratory shall have written procedures that provide specific details concerning how the procedure has been implemented in that laboratory.

5.1 Data Package Contents

- a. Each data package retained by the State or Federal laboratory shall consist of State laboratory forms, USDA collection and report forms, all raw data in the form of chromatograms and integration reports, calculations, and derived data. Additional data requirements consist of two types, instrument and chromatographic. It is intended that all this information be contained in a data package.
 1. Instrument information consists of instrument type and identifier, detector type, injection volume, date and time of injection, dilution information, temperature parameters (injector, detector, oven), analytical column parameters (phase, film thickness, diameter, length), instrument parameters (integration threshold, attenuation, timed events).
 2. Chromatographic information consists of sample ID, analyst name, dilution information, and date and time of injection.
- b. Data submitted to USDA/AMS, Manassas shall include the sample set QA Information Form, Laboratory Information Forms (LIFs), and Sample Information Forms (SIFs).

5.2 Data Submission

Participating laboratories shall submit data to the USDA/AMS Technical Director or their designee. Prior to submission, the data shall be reviewed for completeness and

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accuracy by a minimum of the analyst(s), Technical Program Manager (TPM), and Quality Assurance Unit (QAU) of the laboratory.

5.3 Data Storage

- a. Each participating laboratory shall maintain in its working areas a record system to suit its particular circumstances which assures orderly storage and expedient retrieval of:
 1. all data;
 2. calculations and derived data;
 3. documentation;
 4. protocols;
 5. internal and USDA SOPs (both historical and current);
 6. interim and final reports;
 7. correspondence and other documents relating to interpretation and evaluation of data;
 8. supporting data including but not limited to standard preparation logs, instrument logs, freezer logs, and temperature logs.
- b. Conditions of storage shall minimize deterioration of the documents in accordance with the requirements for the time period of their retention and the nature of the documents.
- c. Where computers or automated equipment are used for the capture, processing, manipulation, recording, reporting, storage or retrieval of data, the laboratory shall ensure that:
 1. Computer software is documented and adequate for use. An example is documentation of Excel spreadsheets and macros. A model set of input data and associated results which have been validated could be constructed. This model could be run periodically to verify correct operation;

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2. Procedures are established and implemented for protecting the integrity of data (such procedures shall include but not be limited to integrity of data entry or capture, data storage, data transmission, and data processing);
3. Computer and automated equipment is maintained to ensure proper functioning and provided with the environmental and operating conditions necessary to maintain the integrity of calibration and test data;
4. Appropriate procedures are established and implemented for the maintenance of security of data including the prevention of unauthorized access or amendment of electronic records.

5.4 Data Archival at the Participating Laboratory

- a. Each data package retained by a State or Federal laboratory should be filed by year, month, and then alphabetically by commodity. Data shall be archived after a data set has been completed and submitted to USDA/AMS, Manassas.
 - b. An individual(s) shall be identified as responsible for the archives.
 - c. Access to archived records shall be monitored and controlled. Use of manual or electronic logs are recommended for documenting access.
 - d. Conditions of storage shall minimize deterioration of the documents in accordance with the requirements for the time period of their retention and the nature of the documents. Locked file cabinets, secured records storage facilities, etc. are all acceptable.
 - e. Data packages shall be maintained at least two years following electronic transmission and before applying for disposition to Federal Records repositories.
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- f. All other documentation shall be archived at the participating laboratory for a minimum of two years following electronic transmission.

5.5 Storage in Federal Record Centers

- a. PDP data as defined in subsection 5.1 shall be transferred to a designated Federal Records Center after the storage requirement specified in Section 5.4.e has elapsed.
- b. Established procedures for transferring PDP data packages shall be followed (refer to May 25, 1994 memorandum, “Procedures of Data Storage for the USDA/AMS/Pesticide Data Program”).

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3/21/01

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Date

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Revision 7	February 2001	QA/Technical Meeting
<ul style="list-style-type: none">• Modified title• Modified purpose for conformity to other SOPs• Updated section 4, "References"• Modified specific procedures statement for conformity to other SOPs• Changed requirements for retention of data other than the data package to a minimum of two years, at which time the laboratory may dispose of records according to internal procedures		